



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Patient Safety and Quality Improvement: Civil Money Penalty Inflation Adjustment

**AGENCY:** Office for Civil Rights, Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, the Office for Civil Rights has determined that an adjustment to the maximum civil money penalty amount for violations of the confidentiality provisions of the Patient Safety and Quality Improvement Rule is not required at this time.

**FOR FURTHER INFORMATION CONTACT:** Andra Wicks, 202-205-2292.

#### **SUPPLEMENTARY INFORMATION:**

##### I. Background

The Patient Safety and Quality and Improvement Act of 2005 (Patient Safety Act), 42 U.S.C. 299b-21 to 299b-26, amended Title IX of the Public Health Service Act, 42 U.S.C. 299 et seq., the authorizing statute for the Agency for Healthcare Research and Quality. The Patient Safety and Quality Improvement Rule, 73 FR 70732 (Nov. 21, 2008), implemented the requirements in the Patient Safety Act. The Rule provides for the listing and delisting of Patient Safety Organizations, the confidentiality and privilege protections of Patient Safety Work Product (PSWP), and procedures for enforcement against violations of the regulations' confidentiality requirements. In particular, under § 3.404, a person who discloses identifiable PSWP in knowing or reckless violation of the

Patient Safety Act and 42 CFR part 3 shall be subject to a civil money penalty (CMP) of not more than \$10,000 for each act constituting a violation.

Congress enacted the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)) (Inflation Adjustment Act), based on its findings that the impact of CMPs had been reduced by inflation and that reducing the impact of CMPs had weakened their deterrent effect. Inflation Adjustment Act section 2, 28 U.S.C. 2461 note. In general, the Inflation Adjustment Act requires Federal agencies to issue regulations to adjust for inflation each CMP provided by law within their jurisdiction. The Inflation Adjustment Act applies to civil penalties found within the Public Health Service Act, such as the Patient Safety Act's CMP provision. The Inflation Adjustment Act directs agencies to issue regulations to adjust CMPs under their authority by October 23, 1996, and to make additional adjustments at least once every four years thereafter based on a specific calculation set forth in the Act. While the Inflation Adjustment Act CMP adjustment requirements apply to most federal statutes, they do not apply to CMPs included in the Social Security Act. The CMPs for title II, subtitle F (Administrative Simplification) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are found at section 1176 of the Social Security Act. Thus, the Inflation Adjustment Act does not require, or provide authority for, the Department to adjust the HIPAA administrative simplification CMPs.

Because the Patient Safety Act was enacted after October 23, 1996, we interpret the Inflation Adjustment Act as requiring the Department to determine whether an adjustment for inflation is necessary for the Patient Safety Act's CMP amount at least

once every four years, beginning from the Patient Safety Act's date of enactment, which was July 29, 2005. Accordingly, on August, 25, 2009, we published a direct final rule to amend the Patient Safety and Quality Improvement Rule by adjusting for inflation the maximum CMP amount for violations of the confidentiality provisions of the Rule. (74 FR 42777 (Aug. 25, 2009).) We chose to use direct final rulemaking because we did not expect to receive any adverse comment on the rule. The Department did not receive any adverse comments, and the direct final rule became effective and the Patient Safety and Quality Improvement Rule was amended on November 23, 2009. The amendment increased the maximum CMP amount from \$10,000 to \$11,000.

## II. No Adjustment is Necessary

In accordance with the Inflation Adjustment Act, the Office for Civil Rights (OCR) has determined that an adjustment to the maximum CMP amount for violations of the confidentiality provisions of the Patient Safety and Quality Improvement Rule is not required at this time.

The Inflation Adjustment Act provides for the adjustment of a penalty amount through a three-step process.<sup>1</sup> First, we calculate an increase in the penalty amount by a “cost-of-living adjustment.” Inflation Adjustment Act section 5(a), 28 U.S.C. 2461 note. The Inflation Adjustment Act defines the cost-of-living adjustment as “the percentage (if any) for each civil monetary penalty by which – (1) the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds (2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil

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<sup>1</sup> Pursuant to the Debt Collection Improvement Act's amendment to the Federal Civil Penalties Inflation Adjustment Act of 1990, the third-step in adjusting a penalty amount requires that the first adjustment of the penalty be limited to ten percent of the penalty amount. This step is not applicable here because the first adjustment to the CMP with respect to the Patient Safety Act occurred on September 24, 2009.

monetary penalty was last set or adjusted pursuant to law.” Inflation Adjustment Act section 5(b), 28 U.S.C. 2461 note. Second, we round the adjustment amount pursuant to the methodology set forth in section 5(a) of the Inflation Adjustment Act, which rounds the increase based on the size of the underlying penalty, as follows:

Any increase determined under this subsection shall be rounded to the nearest—

- (1) multiple of \$10 in the case of penalties less than or equal to \$100;
- (2) multiple of \$100 in the case of penalties greater than \$100 but less than or equal to \$1,000;
- (3) multiple of \$1,000 in the case of penalties greater than \$1,000 but less than or equal to \$10,000;
- (4) multiple of \$5,000 in the case of penalties greater than \$10,000 but less than or equal to \$100,000;
- (5) multiple of \$10,000 in the case of penalties greater than \$100,000 but less than or equal to \$200,000; and
- (6) multiple of \$25,000 in the case of penalties greater than \$200,000.

With respect to step 1 of the adjustment, the Consumer Price Index (CPI) for June of 2012 (the calendar year preceding publication of this Notice) was 229.478. The CPI for June of 2009 (the calendar year the CMP was last adjusted for inflation) was 215.693. The percent change in these CPIs is an increase of 6.39 percent. This leads to an unrounded increase in the Patient Safety Act’s CMP of \$702.90.

With respect to step 2 of the adjustment, we rounded the amount of the increase (\$702.90) to the nearest multiple of \$5,000 because the current maximum CMP is \$11,000, which places it in tier (4) above (i.e., penalties greater than \$10,000 but less than or equal to \$100,000). The nearest multiple of \$5,000 for the \$702.90 increase is zero.

Thus, based on the above, we are not amending 42 CFR 3.404(b) at this time, and the current maximum CMP remains at \$11,000. As required by the Inflation Adjustment Act, we will consider whether an adjustment is needed again in four years.

Dated: September 3, 2013

Leon Rodriguez,  
Director.

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